

Union Calendar No. 90

104TH CONGRESS
1ST SESSION

H. R. 587

[Report No. 104-178]

A BILL

To amend title 35, United States Code, with
respect to patents on biotechnological processes.

JULY 11, 1995

Committed to the Committee of the Whole House on the
State of the Union and ordered to be printed

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IN THE HOUSE OF REPRESENTATIVES

JANUARY 19, 1995

Mr. MOORHEAD (for himself, Mr. BOUCHER, Mr. SENSENBRENNER, Mr. COBLE, Mr. FRANK of Massachusetts, Mr. GALLEGLY, Mr. GOODLATTE, Mr. GEKAS, Mr. BONO, Mr. CANADY of Florida, and Mr. HOKE) introduced the following bill; which was referred to the Committee on the Judiciary

JULY 11, 1995

Additional sponsors: Mr. BERMAN, Ms. DANNER, Mr. ROHRABACHER, Mr. EVANS, Mr. BRYANT of Texas, Mr. KLUG, Mr. McHALE, Mr. FOX of Pennsylvania, Mr. ROYCE, Mr. FORBES, Mrs. MEYERS of Kansas, Ms. ESHOO, Mr. BLUTE, Mr. SAXTON, Mr. ZIMMER, Mr. FATTAH, Mr. CONYERS, and Mr. REED

JULY 11, 1995

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A BILL

To amend title 35, United States Code, with respect to
patents on biotechnological processes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 BIOTECHNOLOGICAL PROCESS PATENTS

4 **SEC. 101. CONDITIONS FOR PATENTABILITY; NONOBVIOUS**
5 **SUBJECT MATTER.**

6 Section 103 of title 35, United States Code, is
7 amended—

8 (1) by designating the first paragraph as sub-
9 section (a);

10 (2) by designating the second paragraph as
11 subsection (c); and

12 (3) by inserting after the first paragraph the
13 following:

14 “(b)(1) Notwithstanding subsection (a), and upon
15 timely election by the applicant for patent to proceed
16 under this subsection, a ‘biotechnological process’ using or
17 resulting in a composition of matter that is novel under
18 section 102 and nonobvious under subsection (a) of this
19 section shall be considered nonobvious if—

20 “(A) claims to the process and the composition
21 of matter are contained in either the same applica-
22 tion for patent or in separate applications having the
23 same effective filing date; and

24 “(B) the composition of matter, and the process
25 at the time it was invented, were owned by the same

1 person or subject to an obligation of assignment to
2 the same person.

3 “(2) A patent issued on a process under paragraph
4 (1)—

5 “(A) shall also contain the claims to the com-
6 position of matter used in or made by that process,
7 or

8 “(B) shall, if such composition of matter is
9 claimed in another patent, be set to expire on the
10 same date as such other patent, notwithstanding
11 section 154.

12 “(3) For purposes of paragraph (1), the term
13 ‘biotechnological process’ means—

14 “(A) a process of genetically altering or other-
15 wise inducing a single- or multi-celled organism to—

16 “(i) express an exogenous nucleotide se-
17 quence,

18 “(ii) inhibit, eliminate, augment, or alter
19 expression of an endogenous nucleotide se-
20 quence, or

21 “(iii) express a specific physiological char-
22 acteristic not naturally associated with said or-
23 ganism;

1 “(B) cell fusion procedures yielding a cell line
2 that expresses a specific protein, such as a
3 monoclonal antibody; and

4 “(C) a method of using a product produced by
5 a process defined by (A) or (B), or a combination
6 of (A) and (B).”.

7 **SEC. 102. PRESUMPTION OF VALIDITY; DEFENSES.**

8 Section 282 of title 35, United States Code, is
9 amended by inserting after the second sentence of the first
10 paragraph the following: “Notwithstanding the preceding
11 sentence, if a claim to a composition of matter is held in-
12 valid and that claim was the basis of a determination of
13 nonobviousness under section 103(b)(1), the process shall
14 no longer be considered nonobvious solely on the basis of
15 section 103(b)(1).”.

16 **SEC. 103. EFFECTIVE DATE.**

17 The amendments made by section 101 shall apply to
18 any application for patent filed on or after the date of
19 enactment of this Act and to any application for patent
20 pending on such date of enactment, including (in either
21 case) an application for the reissuance of a patent.